

## PATIENT INFORMATION LEAFLET

### **Laxamot 667 mg/ml Syrup** **For oral use.**

- **Active substance(s):** The solution of 1000 ml contains 667 gram lactulose (derived from cow milk).
- **Excipient(s):** LAXAMOT does not contain any excipients, but may contain small amounts of other sugars (e.g. lactose, galactose, epilactose, fructose).

**Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

### **What is in this leaflet?**

1. ***What LAXAMOT is and what it is used for?***
2. ***What you need to know before you use LAXAMOT***
3. ***How to use LAXAMOT?***
4. ***Possible side effects***
5. ***How to store LAXAMOT?***

### **1. What LAXAMOT is and what it is used for?**

LAXAMOT is a clear, viscous, colorless to brownish yellow solution used by the oral route. It is presented in a 300 ml high density polyethylene (HDPE) bottle closed with polyethylene (PE) cap packaged together with 30 ml polypropylene (PP) measuring cup.

LAXAMOT contain a laxative (stool softeners) called lactulose (derived from cow milk). Lactulose make the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body. It is used for the treatment of the following conditions:

- Constipation: Ensure that the colon acquires normal physiological rhythm
- In cases where the stool consistency is medically desired to be soft (after surgical procedures for hemorrhoids, colon or anus)
- A liver disorder called hepatic encephalopathy (HE) that causes mental confusion, tremor, a decrease in consciousness including coma: It is used for treatment and prophylaxis before hepatic coma or coma.

### **2. What you need to know before you use LAXAMOT**

#### **Do not use LAXAMOT**

- if you are allergic to active substance (lactulose) or any of the other ingredients.

- if you suffer from rarely seen galactosaemia (congenital deficiency of galactose metabolizing enzyme)
- Blockage that can cause constipation in the digestive system, risk of perforation or perforation in the digestive system organs

If any of the above applies to you, do not use LAXAMOT.

If you are not sure, consult your doctor or pharmacist before using LAXAMOT.

If you have previously been told by your doctor that you have an intolerance to some sugars, consult your doctor before using this medicinal product.

### **Warnings and precautions**

Consult your doctor or pharmacist before using LAXAMOT, if you have any complaints or illnesses, especially including the following.

- If you have an unexplained abdominal pain
- If you do not digest lactose (milk sugar)
- If you have diabetes

If you have diabetes and are treated for HE (Hepatic encephalopathy), your LAXAMOT dose will be higher. This high dose contains a lot of sugar. Therefore, it may need to adjust the dose of medicine which you use to treat diabetes.

Long-term use of unadjusted doses (exceeding 2-3 soft stools per day) and misuse can lead to diarrhea and disturbance of the electrolyte balance.

During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 liters per day, equal to 6-8 glasses).

Consult your doctor if you do not feel better or if you feel worse after a few days of treatment

### **Use in children**

In special circumstances your doctor may prescribe LAXAMOT for a child or baby. In these cases, your doctor should follow the treatment carefully. LAXAMOT should be given to babies and small children only under the necessary medical conditions, as they may affect the normal reflexes for passing stools.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

### **LAXAMOT with food and drink**

LAXAMOT can be taken with or without food. There are no restrictions on what you can eat or drink.

### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine.*

If you are pregnant or have the potential to become pregnant, consult your doctor or pharmacist before using this medicine.

LAXAMOT can be used during pregnancy if necessary.

*Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.*

### ***Breast-feeding***

*Consult your doctor or pharmacist before taking this medicine.*

If you are breastfeeding, consult your doctor or pharmacist before using this medicine.

LAXAMOT can be used during breastfeeding if necessary.

### **Driving and using machines**

LAXAMOT has no or negligible influence on the ability to drive and use machines.

### **Important information about some of the excipients of LAXAMOT**

LAXAMOT may contain small amounts of milk sugar (lactose), galactose, epilactose or fructose. If you have previously been told by your doctor that you have an intolerance to some sugars, you should consult your doctor before taking this medicinal product.

### **Other medicines and LAXAMOT**

Interaction studies with other medicinal products have not been conducted.

*If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.*

## **3. How to use LAXAMOT?**

### **• Instructions for use and dosage/frequency of administration:**

Always use LAXAMOT exactly as your doctor has told you. Check with your doctor if you are not sure.

- Use LAXAMOT with measuring cup.
- You can mix LAXAMOT with fruit juice, milk or water. It is recommended to drink plenty of fluids (about 6-8 glasses during the day).
- Swallow the medicine quickly. Do not keep it in your mouth. Because LAXAMOT can cause dental decay, especially when used for long periods of time.
- It can take 2-3 days until the desired effect has been achieved.
- Your doctor will adjust your dose according to your responses to the medicine

Dosing in constipation or in cases where the stool consistency is medically desired to be soft:

LAXAMOT may be given as a single daily dose or in two divided doses. Your doctor will tell you how often you need to use it.

	<b>Starting dose daily</b>	<b>Maintenance dose daily</b>
<b>Adults and adolescents</b>	15 – 45 ml	15 – 30 ml
<b>Children (7-14 years)</b>	15 ml	10- 15 ml
<b>Children (1-6 years)</b>	5 – 10 ml	5 – 10 ml
<b>Infants under 1 year</b>	up to 5 ml	up to 5 ml

Dosing in HE (hepatic encephalopathy) (for adults only):

Adults:

Starting dose: 3 to 4 times daily 30-45 ml

This dose can be adjusted by your doctor to provide a soft stool 2-3 times a day.

### **• Route of administration and method:**

LAXAMOT is only for oral use.

When a single daily dose is prescribed, the dose should be taken regularly and at the same time of day (e.g. during breakfast).

- **Different age groups:**

- Use in children:**

- Information on the dose of use in children of different age groups is given in the table above.

- The use of laxative preparations in children and babies should be under exceptional circumstances and under your doctor control, as these may affect the normal defecation reflex.

- Do not give LAXAMOT to children under the age of 14 without consulting your doctor and your doctor's supervision.

- No information is available for children with HE (hepatic encephalopathy) (newborn to 18 years of age)

- Use in elderly:**

- There are no specific dose recommendations.

- **Special cases of use:**

- Kidney/liver failure:**

- There are no specific dose recommendations.

*If you have impression that the effect of LAXAMOT is very strong or weak, tell a doctor or pharmacist.*

**If you use more LAXAMOT than you should:**

*If you take more LAXAMOT than you should, stop using medicine and tell your doctor or pharmacist*

If you take more LAXAMOT than you should, diarrhea and abdominal pain may occur. In this case, treatment should be discontinued or the dose should be reduced to an adequate level as prescribed by your doctor.

Extensive fluid loss by diarrhea or vomiting may require treatment. In these cases please consult your doctor.

**If you forget to use LAXAMOT:**

*Do not take a double dose to make up for a forgotten dose.*

If you forget to use a dose of LAXAMOT, do not worry. Just take the next dose at the usual time.

**If you stop using LAXAMOT:**

Do not stop or change your treatment without consulting your doctor.

If you have any further questions on the use of the medicine, consult your doctor or pharmacist.

**4. Possible side effects?**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

The following side effects have been reported for LAXAMOT:

**Very common**

- Diarrhea

**Common**

- Flatulence
- Nausea
- Vomiting
- Abdominal pain

**Uncommon**

- Electrolyte imbalance due to diarrhea

Flatulence may occur during the first few days of treatment. Generally, it disappears after a couple of days. When dosages higher than instructed are used, abdominal pain and diarrhea may occur. In such a case the dosage should be decreased.

If you use high doses (as doses normally used in the treatment of hepatic encephalopathy, HE) for a long time, you may experience electrolyte imbalance due to diarrhea.

*If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.*

**5. How to store LAXAMOT**

*Keep LAXAMOT in the original package and out of the reach and sight of children.*

Store at room temperature below 25°C in original packaging.

**Use in accordance with expiry date.**

*Do not use LAXAMOT after the expiry date which is stated on the package.*

***Marketing authorization holder:***

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Türkiye

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

[info@berko.com.tr](mailto:info@berko.com.tr)

***Manufacturer:***

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Türkiye

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

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